In response to the above rejections, Applicants have amended the claims which, when considered with the following remarks, is deemed to place the present application in condition for allowance or at least in better condition for appeal. Favorable consideration of all pending claims is respectfully requested.

In the first instance, Applicants respectfully submit that the Sequence Listing has been amended to correct certain typographical errors. More specifically, Applicants have corrected two typographical errors in the nucleotide sequence of SEQ ID NO: 6 (human bcl-w) at nucleotide position 301, 404 and 405, as indicated in the attached marked-up copy of the amended Sequence Listing. Furthermore, the protein sequence in SEQ ID NO: 7 has been amended to correct two clerical errors appearing at positions 101 and 135. In addition, Applicants have corrected certain typographical errors in the nucleotide sequence of SEQ ID NO: 8 (murine bcl-w), as indicated in the attached marked-up copy of the amended Sequence Listing. The protein sequence in SEQ ID NO: 9 has been amended to correct certain clerical errors, as indicated in the attached marked-up copy of the amended sequence listing.

Applicants respectfully submit that the foregoing amendment does not introduce new matter. More specifically, the protein sequence of SEQ ID NO: 7 (human bcl-w) as amended is set forth in Figure 8 as originally filed. The protein sequence of SEQ ID NO: 9 (murine bcl-w) as amended is set forth in Figure 1 as originally filed. In addition, these protein sequences find support in Figures 9A and 9B of the priority document, Australian Provisional Application PN8965, filed on March 27, 1996. A courtesy copy of such priority document is enclosed for the Examiner's convenience (Exhibit A). The nucleotide sequences of SEQ ID NO: 6 and SEQ ID NO: 8 as amended are also disclosed in Figure 9A and 9B, respectively, of the priority document.

Applicants further respectfully submit that the originally filed Figures 9A to 9B(iv), which set forth the nucleotide and protein sequences of human bcl-w and murine bcl-w, contain the same typographical errors as the original Sequence Listing. Accordingly, Applicants submit herewith substitute sheets of Figures 9A and 9B to replace the drawing sheets of Figures 9A to 9B(iv) originally filed. The substitute drawing of Figure 9B discloses the nucleotide sequence (SEQ ID NO: 6) and the encoded protein sequence (SEQ ID NO: 7) of human bcl-w. The substitute drawing of Figure 9B discloses the nucleotide sequence (SEQ ID NO: 8) and the encoded protein sequence (SEQ ID NO: 9) of murine bcl-w. These substitute sheets of drawings do not introduce new matter and are fully supported by the application as filed and by the priority document.

Furthermore, Applicants respectfully submit that the foregoing amendment does not introduce matters that require an additional search on the part of the Examiner. In particular, SEQ ID NO: 7 (human bcl-w) is only amended by two amino acid residues of the total 193 amino acid residues. SEQ ID NO: 9 (murine bcl-w) is only amended by 9 out of 193 amino acid molecules. Therefore, the Examiner's initial search for sequences having at least about 47% similarity to the original SEQ ID NO: 7 or original SEQ ID NO: 9, and for nucleotide sequences encoding proteins having at least about 47% similarity to the original SEQ ID NO: 7 or original SEQ ID NO: 9, would have been sufficient to capture the current corrected version of SEQ ID NO: 7 and SEQ ID NO: 9, as well as the corrected versions of the encoding nucleotide sequences SEQ ID NO: 6 and SEQ ID NO: 9.

Turning to the claims, the Examiner rejects claims 1-4 under 35 U.S.C. §112, first paragraph as allegedly not enabled. The Examiner admits that the specification is enabling for an isolated nucleic acid molecule comprising SEQ ID NO: 6 or 8 which encodes the amino acid sequence of SEQ ID NO: 7 or 9. However, the Examiner contends that the specification does

not provide enablement for all nucleic acid molecules encompassed by the claims. The Examiner states that the specification does not disclose any derivative of SEQ ID NO: 6 or 8, or a nucleic acid molecule encoding an amino acid sequence having at least 47% similarity to SEQ ID NO: 7 or 9, or a nucleic acid molecule which hybridizes under low stringency conditions to SEQ ID NO: 6 or 8 and which elicits a Bcl-w-related activity. It is the Examiner's opinion that it would take undue experimentation for those skilled in the art to practice the claimed invention.

Applicants respectfully disagree with the Examiner. Applicants respectfully submit that the present specification adequately teaches the molecules as claimed, including derivative and homologous sequences of SEQ ID NO: 6 or 8 that enhance cell survival. For example, the specification teaches the human bcl-w gene (SEQ ID NO: 6) and the murine bcl-w gene (SEQ ID NO: 8). The specification further teaches that the human Bcl-w protein and the murine Bcl-w share about 90% similarity. Moreover, the specification provides specific exemplification demonstrating that expression of the bcl-w gene enhances cell survival. See pages 35-36 of the specification. In light of the present teaching, those skilled in the art can isolate a nucleic acid molecule that either hybridizes to SEQ ID NO: 6 or 8, or encodes a protein that shares at least about 47% similarity to SEQ ID NO: 7 or 9, and determine whether the isolated molecule enhances cell survival. It is respectfully submitted that the experimentation required for those skilled in the art to make and use the claimed molecule is not undue.

However, in an effort to favorably advance the prosecution of the present case,

Applicants have canceled claims 1-4 without prejudice, rendering the rejection thereof moot.

Applicants reserve the right to pursue the subject matter of these canceled claims in a continuing application.

Applicants have also added claims 21-24, directed to nucleic acid molecules comprising SEQ ID NO: 6 or SEQ ID NO: 8, or encoding a protein having a sequence as set

forth in SEQ ID NO: 7 or SEQ ID NO: 9. As the Examiner has acknowledged in the Final Action, the specification is enabling for these nucleic acid molecules.

Accordingly, withdrawal of the rejection of claims 1-4 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1 and 4 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 5,789,201 ("the '201 patent"). According to the Examiner, the '201 patent teaches nucleotide sequences encoding a bcl-2 homolog (bcl-y). The Examiner contends that the sequence search report provided by the Examiner shows that the human bcl-y gene of the '201 patent matches 97.4% to SEQ ID NO: 6 (human bcl-w) of the claimed invention, and 85% to SEQ ID NO: 8 (murine bcl-w) of the present invention; and that the human Bcl-y protein of the '201 patent matches 98.7% to SEQ ID NO: 7 (human Bcl-w).

It is respectfully submitted that the cancellation of claims 1-4 renders the rejection moot. Withdrawal of the rejection is therefore respectfully requested.

Applicants further submit that the nucleic acid molecules of claims 21-24 are not taught by the '201 patent. Applicants have provided herewith **Exhibit B**, illustrating the differences between the bcl-w sequences of the present application and the bcl-y sequences of the '201 patent. At page 1 of Exhibit B, the human bcl-w (SEQ ID NO: 7), the murine bcl-w (SEQ ID NO: 9), the human bcl-y of the '201 patent (SEQ ID NO: 4 of the '201 patent) and the rat bcl-y of the '201 patent are compared with one another. It is observed that the human bcl-w protein of the present application differs from the human bcl-y of the '201 patent at amino acid position 15, with Ala in human bcl-w and Glu in human bcl-y. The human bcl-w protein differs from the rat bcl-y of the '201 patent at amino acid position 7 ("A" in human bcl-w and "T" in rat bcl-y), position 124 ("E" in human bcl-w and "D" in rat bcl-y), and position 128 ("A" in human bcl-w and "T" in rat bcl-y). It is further observed that the murine bcl-w protein of the present

application differs from the human bcl-y of the '201 patent at amino acid position 7 ("T" in murine bcl-w and "A" in human bcl-y), position 15 ("A" in murine bcl-w and "E" in human bcl-y), and position 124 ("D" in murine bcl-w and "E" in human bcl-y). The murine bcl-w protein of the present application also differs from the rat bcl-y of the '201 patent at amino acid position 128 ("A" in murine bcl-w and "T" in rat bcl-y). Accordingly, protein sequences of SEQ ID NO: 7 and SEQ ID NO: 9 of the present application are not taught by the '201 patent, nor are the nucleic acid molecules encoding the protein of SEQ ID NO: 7 or SEQ ID NO: 9 (i.e., the subject matter of claims 21-22) taught by the '201 patent.

At page 2 of Exhibit B, the nucleotide sequence of the human bcl-w gene (SEQ ID NO: 6 of the present application) is compared with the human bcl-y and rat bcl-y genes of the '201 patent. Those nucleotides in the bcl-y genes which differ from the human bcl-w gene are indicated underneath the human bcl-w sequence. Clearly, the human bcl-w gene (SEQ ID NO: 6) of the present application is distinct from the human bcl-y and rat bcl-y genes of the '201 patent. Therefore, claim 23, drawn to a nucleic acid molecule comprising SEQ ID NO: 6, is not taught by the '201 patent.

Page 3 of Exhibit B illustrates the differences between the murine bcl-w gene (SEQ ID NO: 8) of the present application and the bcl-y genes of the '201 patent. Clearly, the murine bcl-w gene (SEQ ID NO: 8) of the present application is distinct from the human bcl-y and rat bcl-y genes of the '201 patent. Therefore, claim 24, drawn to a nucleic acid molecule comprising SEQ ID NO: 8 is not taught by the '201 patent.

Attached hereto is a marked-up copy of the amendment to the claims and to the Sequence Listing, entitled "Version with markings to show changes made"; a substitute paper and computer-readable copy of the Sequence Listing; a statement under §1.821(f) verifying that the content of the substitute paper copy and the substitute computer-readable copy of the

Sequence Listing are the same; substitute sheets for Figures 9A and Figures 9B; Exhibit A and Exhibit B.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

Frank S. DiGiglio Registration No. 31,346

Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, New York 11530 Telephone: 516-742-4343 FSD/XZ:ab

Enclosures: Marked up version of the amendment to the claims and the Sequence Listing

Substitute paper and computer-readable copy of the Sequence Listing

Statement under §1.821(f)

Substitute sheets of Figures 9A and 9B

Exhibit A: Priority Document (Australian Provisional Application PN8965)

Exhibit B: Comparison of bcl-w and bcl-y sequences



Serial No:

09/155,327

Date:

August 9, 2001

# **VERSION WITH MARKINGS TO SHOW CHANGES MADE**

### In the claims:

Claims 1-4 have been canceled without prejudice.

### Claims 21-24 have been added:

- 21. An isolated nucleic acid molecule, wherein said nucleic acid molecule encodes a protein comprising an amino acid sequence as set forth in SEQ ID NO: 7.
- 22. An isolated nucleic acid molecule, wherein said nucleic acid molecule encodes the amino acid sequence as set forth in SEQ ID NO: 9.
- 23. An isolated nucleic acid molecule wherein said nucleic acid molecule comprises the nucleotide sequence as set forth in SEQ ID NO: 6.
- 24. An isolated nucleic acid molecule wherein said nucleic acid molecule comprises the nucleotide sequence as set forth in SEQ ID NO: 8.

## In the Sequence Listing:

The sequences in SEQ ID NO: 6-9 have been amended as follows:

# AUG 2 1 2001 TECH CENTER 1600/2900

/	OIPE
	AUG 1 3 2001 H
PATE	<b>,</b>
4	& TRADEMPAY

<220>

<210> 6 <211> 583

<212> DNA <213> HUMAN

<221> CDS

<222> (1)..(579)

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1 5 10 15

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Phe Val Gly Tyr Lys Leu Arg Gln Lys Gly Tyr Val Cys Gly Ala Gly
20 25 30

gct gga gat gag ttc gag acc cgc ttc cgg cgc acc ttc tct gat ctg 192
Ala Gly Asp Glu Phe Glu Thr Arg Phe Arg Arg Thr Phe Ser Asp Leu
50 55 60

gcg gct cag ctg cat gtg acc cca ggc tca gcc cag caa cgc ttc acc 240
Ala Ala Gln Leu His Val Thr Pro Gly Ser Ala Gln Gln Arg Phe Thr
65 70 75 80

cag gtc tcc gac gaa ctt ttt caa ggg ggc ccc aac tgg ggc cgc ctt 288
Gln Val Ser Asp Glu Leu Phe Gln Gly Gly Pro Asn Trp Gly Arg Leu
85 90 95

gta gcc ttc ttt / tc ttt ggg gct gca ctg tgt gct gag agt gtc aac 336

Val Ala Phe Phe Lew Phe Gly Ala Ala Leu Cys Ala Glu Ser Val Asn
100 105 110

aag gag atg gaa cca ctg gtg gga caa gtg cag gag tgg atg gtg gcc 384
Lys Glu Met Glu Pro Leu Val Gly Gln Val Gln Glu Trp Met Val Ala
115 120 125

	ctg	gag	acg	cgg	ctg	ct g <b>z</b> ź	gac	tgg	atc	cac	agc	aqt	aaa	aac	taa	432
	Leu															
	130					135					140					
	gag															480
	Glu	Phe	Thr	Ala	Leu	Tyr	Gly	Asp	Gly	Ala	Leu	Glu	Glu	Ala	Arg	
145					150					155					160	
	ctg															528
Arg	Leu	Arg	Glu	Gly	Asn	Trp	Ala	Ser	Val	Arg	Thr	Val	Leu	Thr	Gly	
				165					170					175		
gcc	gtg	gca	ctg	ggg	gcc	ctg	gta	act	gta	ggg	gcc	ttt	ttt	gct	agc	576
Ala	Val	Ala	Leu	Gly	Ala	Leu	Val	Thr	Val	Gly	Ala	Phe	Phe	Ala	Ser	
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Lys																
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Gln Val Ser Asp Glu Leu Phe Gln Gly Gly Pro Asn Trp Gly Arg Leu
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Val Ala Phe Phe Hew Phe Gly Ala Ala Leu Cys Ala Glu Ser Val Asn
100 105 110

Lys Glu Met Glu Pro Leu Val Gly Gln Val Gln Glu Trp Met Val Ala 115 120 125

Tyr Leu Glu Thr Arg Leu Val Asp Trp Ile His Ser Ser Gly Gly Trp
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1 10 15

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			tat													96
Phe	Val	Gly	Tyr	Arg	Leu	Arg	Gln	Lys	Gly	Tyr	Val	Cys	Gly	Ala	Gly	
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		_	Gly													
		35	_				40					45		_		
		33														
aat	~~~	<b>~</b> ~ ~	gag	+++	aza	200	cat	ttc	cac	cac	acc	ttc	tct	aac	cta	192
_		_														102
Ата	_	Asp	Glu	Pne	GIU		Arg	Pne	Arg	Arg		rne	Ser	Asp	теи	
	50					55					60					
-	_	_	cta													240
Ala	Ala	Gln	Leu	His	Val	Thr	Pro	Gly	Ser	Ala	Gln	Gln	Arg	Phe	Thr	
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cag	gtt	tcc	gac	gaa	ctt	ttc	caa	ggg	ggc	cct	aac	tgg	ggc	cgt	ctt	288
Gln	Val	Ser	Asp	Glu	Leu	Phe	Gln	Gly	Gly	Pro	Asn	Trp	Gly	Arg	Leu	
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_			Phe													
Val	Ala	rne		vaı	rne	GIY	AIG	105	пец	Cys	7114	010	110		11011	
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									g				9,			204
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tac	ctg	gag	aca	cgt	ctg	gct	gac	tgg	atc	cac	agc	agt	ggc	ggc	tgg	432
Tyr	Leu	Glu	Thr	Arg	Leu	Ala	Asp	Trp	Ile	His	Ser	Ser	Gly	Gly	Trp	
	130					135					140					
	_												•			
aca	ga <b>d</b>	ttc	aca	act	cta	tac	aaa	gac	ggg	gcc	ctg	gag	ga <b>≴</b>	gca	cgg	480
	-		Thr													
	Glu	2			150		1	- 1-		155			Gli		160	
140					200											
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Arg	Leu	Arg	GLu	GLy	Asn	Trp	Ala	ser	Val	Arg	Thr	val	VIIII	ату	MI a	→(th next page)
				165					170	J		•	LEM	175	1	7

aag tg**a** 

page)

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Lys

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	_			_	_		_	_			-	_		gct Ala		96
					_	_	_	_	_			-	_	cgg Arg	_	144
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aag Lys	tgaa	ā														583

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aag Lys	tga															582